

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (original) A method of treatment of a blood vessel, comprising:
advancing an evacuation sheath assembly into the blood vessel;
stopping normal antegrade blood flow in the blood vessel proximate to the stenosis;
advancing a therapeutic catheter into the blood vessel;
treating the stenosis with the therapeutic catheter;
advancing an infusion catheter to a location distal to the stenosis;
infusing the blood vessel with a fluid supplied by the infusion catheter; and
inducing retrograde flow within the blood vessel to carry embolic material dislodged during treating into the evacuation sheath assembly.
2. (original) The method of claim 1, wherein advancing the infusion catheter includes advancing the infusion catheter through a distal end of the evacuation sheath assembly.
3. (original) The method of claim 1, wherein stopping blood flow includes creating a first seal between a distal portion of the evacuation sheath assembly and the blood vessel.
4. (original) The method of claim 3, wherein stopping blood flow further comprises creating a second seal between a guide catheter and a proximal portion of the evacuation sheath assembly.

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5. (original) The method of claim 1, wherein inducing retrograde flow includes applying a vacuum through the evacuation sheath assembly.
6. (original) The method of claim 1, wherein treating the stenosis includes advancing an angioplasty catheter to the stenosis.
7. (original) The method of claim 1, wherein treating the stenosis includes advancing a stent delivery system to the stenosis.
8. (original) The method of claim 1, wherein inducing retrograde flow includes venting pressure in a collection device in fluid communication with the blood vessel with normal antegrade blood flow stopped.
9. (original) The method of claim 8, wherein inducing retrograde flow further includes applying suction to the collection device.
10. (original) The method of claim 1, wherein the blood vessel is a coronary artery.
11. (original) The method of claim 1, wherein the blood vessel is a saphenous vein graft.
12. (original) The method of claim 1, wherein the step of stopping normal antegrade flow is performed prior to advancing a device across the stenosis..
13. (original) The method of claim 1, wherein infusing the blood vessel with a fluid includes delivering a fluid through at least one infusion port of the infusion catheter.
14. (original) The method of claim 1, wherein infusing the blood vessel with a fluid includes delivering the fluid to a location distal to the treated stenosis.

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15. (original) The method of claim 1, wherein infusing the blood vessel with a fluid includes infusing saline into the blood vessel.

16. (original) The method of claim 1, wherein infusing the blood vessel with a fluid includes infusing whole blood into the blood vessel.

17. (original) The method of claim 1, wherein infusing the blood vessel with a fluid includes infusing radiopaque dye into the blood vessel.

18. (original) The method of claim 1, wherein advancing the evacuation sheath assembly includes advancing the evacuation sheath assembly through a guide catheter, and further comprising applying a vacuum to the guide catheter prior to infusing the fluid.

19. (original) The method of claim 1, further comprising inducing retrograde flow prior to advancing the infusion catheter to move debris proximal to the treated stenosis.

20. (original) A method for treating a blood vessel, comprising:
positioning a guide catheter proximate to the blood vessel;
positioning an evacuation sheath assembly within the blood vessel;
stopping normal antegrade blood flow in the blood vessel proximate to the site;
advancing an interventional catheter into the blood vessel to treat the site of the blood vessel;
occluding blood flow at the site with the interventional catheter;

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permitting antegrade blood flow around the guide catheter and evacuation sheath assembly toward the treatment site while blood flow is occluded by the interventional catheter; and

applying a vacuum to the evacuation sheath assembly to carry embolic debris and antegrade blood flow into the evacuation sheath while blood flow is occluded by the interventional catheter.

21. (original) The method of claim 20, wherein stopping normal antegrade blood flow is performed prior to advancing a device across the treatment site.

22. (original) The method of claim 20, further including applying a vacuum to the evacuation sheath assembly prior to occluding blood flow.

23. (original) The method of claim 22, wherein the blood vessel is a coronary artery.

24. (original) The method of claim 22, wherein the blood vessel is a saphenous vein graft.

25. (original) The method of claim 22, further comprising treating the site in the blood vessel, the treating including inflating a balloon.

26. (original) The method of claim 25, further comprising deflating the balloon after treating the area of the blood vessel.

27. (original) The method of claim 26, wherein occluding blood flow includes re-inflating the balloon of the interventional catheter.

28. (original) The method of claim 22, wherein stopping normal antegrade blood flow includes creating a first seal between a distal portion of the evacuation

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sheath assembly and the blood vessel and includes creating a second seal between a proximal portion of the evacuation sheath assembly and the guide catheter.

29. (original) The method of claim 28, wherein permitting antegrade blood flow includes releasing the first seal.

30. (original) The method of claim 22, wherein advancing the interventional catheter includes advancing the interregional catheter through the evacuation sheath assembly.

31. (original) An evacuation sheath assembly, comprising:

an elongate hollow member having proximal and distal ends, first and second lumens, and first and second sealing members, wherein the proximal end is flared, and wherein the first lumen is an evacuation lumen configured to be placed in fluid communication with a bloodstream and wherein the second lumen is an inflation lumen in fluid communication with at least one of the first and second sealing members; and

a shaft in fluid communication with the inflation lumen and configured to connect to an inflation source.

32. (original) The assembly of claim 31, wherein the first and second sealing members are balloons.

33. (original) The assembly of claim 31, wherein the first and second sealing members are elastomeric.

34. (original) The assembly of claim 31, wherein the first sealing member is located on a proximal portion of the elongated hollow member and the second sealing member is located on a distal portion of the elongated hollow member.

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35. (original) An evacuation sheath assembly, comprising:

an elongate hollow member supported by a kink-resisting coil and having first and second lumens, and first and second sealing members, wherein the first lumen is an evacuation lumen configured to be placed in fluid communication with a bloodstream and wherein the second lumen is an inflation lumen in fluid communication with at least one of the first and second sealing members; and

a shaft in fluid communication with the inflation lumen and configured to connect to an inflation source.

36. (original) The assembly of claim 35, wherein a distal end of the elongated hollow member is perpendicular to a longitudinal axis of the elongated hollow member.

37. (original) The assembly of claim 36, wherein one of said first and second sealing members is adjacent the distal end of the elongated hollow member.

38. (original) A combination for isolating fluid communication between a blood vessel and a catheter, comprising:

a catheter having a lumen;

an obturator having a proximal end and a distal end, wherein the distal end includes a distal tip having a first tapering diameter; and

an evacuation sheath assembly configured to move within the lumen of the catheter and having an evacuation lumen and first and second sealing members, wherein the evacuation sheath assembly has a second diameter greater than the first tapering diameter.

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39. (original) The combination of claim 38, wherein the distal tip is a flexible, steerable tip.

40. (original) A combination for isolating fluid communication between a blood vessel and a catheter, comprising:

a catheter having a lumen; and

an evacuation sheath assembly configured to move within the lumen of the catheter and having an evacuation lumen and first and second sealing members, wherein a proximal end of the evacuation lumen is flared.

41. (original) The combination of claim 40, wherein the flared end of the evacuation lumen is configured to isolate fluid communication between the blood vessel and the catheter lumen.

42. (original) The combination of claim 40, wherein the flared end of the evacuation sheath assembly is configured to seal against the lumen of the catheter.

43. (original) The combination of claim 40, wherein the first sealing member includes a proximal portion of the evacuation sheath assembly configured to seal against the lumen of the catheter.

44. (original) The combination of claim 40, wherein the second sealing member is located on a distal portion of the evacuation sheath assembly.

45. (original) The combination of claim 40, wherein the first and second sealing members include expandable surfaces.

46. (original) The combination of claim 40, wherein the second sealing member is configured to create a seal between the evacuation sheath assembly and the blood vessel.

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47. (original) The combination of claim 40, wherein a distal end of the evacuation lumen is perpendicular to a longitudinal axis of the evacuation lumen.

48. (original) The combination of claim 47, wherein the second sealing member is adjacent the distal end of the evacuation lumen.

49. (original) A combination for isolating fluid communication between a blood vessel and a catheter, comprising:

a catheter having a lumen;

an obturator having a proximal end and a distal end, wherein the distal end includes a balloon and distal tip having a first tapering diameter; and

an evacuation sheath assembly configured to move within the lumen of the catheter and having an evacuation lumen and first and second sealing members, wherein the evacuation sheath assembly has a second diameter greater than the first tapering diameter.

50. (original) The combination of claim 49, wherein the balloon is configured to form a seal with the evacuation lumen.

51. (original) The combination of claim 49, wherein the balloon is configured to expand a treatment site prior to treatment.

52. (original) A method of treatment of a blood vessel, comprising:

advancing a guide catheter proximate to the blood vessel;

advancing an evacuation sheath assembly through the guide catheter and into the blood vessel while retaining a proximal portion of the evacuation sheath assembly within the guide catheter;

at least partially occluding the coronary sinus;

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creating a seal between a distal portion of the evacuation sheath assembly and the blood vessel;

stopping normal antegrade blood flow within the blood vessel;

treating a stenosis within the blood vessel;

causing retrograde flow within the blood vessel to thereby remove embolic material dislodged during the treating and carried by the retrograde flow into the evacuation sheath assembly; and

re-establishing normal antegrade blood flow within the blood vessel.

53. (original) The method of claim 52, further comprising creating a second seal between the proximal portion of the evacuation sheath assembly and the guide catheter.

54. (original) The method of claim 52, wherein at least partially occluding the coronary sinus includes advancing an occlusion catheter into the coronary sinus.

55. (original) The method of claim 52, wherein at least partially occluding the coronary sinus includes expanding a balloon of an occlusion catheter within the coronary sinus.

56. (original) An evacuation sheath assembly, comprising:

an elongated tube defining an evacuation lumen having open proximal and distal ends and an inflation lumen having an open proximal end and a closed distal end; and

at least one inflatable sealing surface in fluid communication with the inflation lumen;

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wherein the open distal end of the evacuation lumen is perpendicular to a longitudinal axis of the evacuation lumen.

57. (original) - A combination for isolating fluid communication between a blood vessel and a catheter, comprising:

a guide catheter having a lumen;

an evacuation sheath assembly configured to move within the lumen of the guide catheter and having an evacuation lumen and first and second sealing surfaces; and

an infusion catheter assembly having an infusion lumen and at least one infusion port, the infusion catheter assembly being configured to move within the evacuation lumen.

58. (original) An infusion catheter assembly comprising:

a proximal shaft portion having a proximal infusion lumen; and

a distal shaft portion connected to a distal end of the proximal shaft portion, the distal shaft portion including a distal infusion lumen in flow communication with the proximal infusion lumen, at least one infusion port, and a guidewire lumen, wherein the guidewire lumen is shorter than the combined length of the proximal and distal infusion lumens.

59. (original) A method of treatment of a blood vessel, comprising:

advancing an evacuation sheath assembly into the blood vessel;

maintaining elevated pressure in the coronary sinus;

stopping normal antegrade blood flow in the blood vessel proximate to the stenosis;

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treating the stenosis; and

inducing retrograde blood flow within the blood vessel to carry embolic material dislodged during treating into the evacuation sheath assembly.

60. (original) The method of claim 59, wherein stopping normal antegrade blood flow is performed prior to advancing a device across the stenosis.

61. (original) The method of claim 59, wherein maintaining elevated pressure in the coronary sinus includes preventing closure of venous valves.

62. (original) The method of claim 59, wherein maintaining elevated pressure in the coronary sinus includes advancing an occlusion catheter into the coronary sinus.

63. (original) The method of claim 62, wherein maintaining elevated pressure in the coronary sinus further includes inflating an occlusion balloon in the coronary sinus.

64. (original) The method of claim 59, wherein maintaining elevated pressure in the coronary sinus includes occluding the coronary sinus prior to stopping normal antegrade blood flow.

65. (original) The method of claim 59, wherein treating the stenosis includes inflating a stent balloon, and wherein maintaining elevated pressure in the coronary sinus includes occluding the coronary sinus prior to deflating the stent balloon.

66. (original) A combination for isolating fluid communication between a blood vessel and a catheter, comprising:

a guide catheter having a lumen;

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an evacuation sheath assembly configured to move within the lumen of the guide catheter and having an evacuation lumen and first and second sealing surfaces; and

an infusion catheter assembly configured to move within the evacuation lumen.

67. (original) A method of treating a blood vessel, comprising:
advancing an evacuation sheath assembly into the blood vessel;
creating a first seal between the blood vessel and the evacuation sheath assembly;
advancing an interventional device across a stenosis to be treated;
treating the stenosis;
inducing retrograde flow at the stenosis;
establishing a second seal between the blood vessel and the interventional device;
releasing the first seal to permit antegrade blood flow toward the treatment site; and
applying suction to carry embolic material dislodged during treating and the antegrade blood flow into the evacuation sheath assembly.

68. (original) The method of claim 67, wherein treating the stenosis includes expanding a balloon of the interventional device.

69. (original) The method of claim 68, wherein expanding the balloon includes forming a seal between the blood vessel and the balloon.

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70. (previously presented) The method of claim 69, wherein inducing retrograde flow includes deflating the balloon.

71. (new) A method of treating a lesion within a blood vessel, comprising:
advancing an evacuation sheath into the blood vessel;
prior to advancing a device across the lesion to be treated, deploying a first occlusive element on a distal portion of the evacuation sheath and a second occlusive element on a second portion of the evacuation sheath proximal to the distal portion to stop substantially all blood flow in the vessel proximate to the lesion;
treating the lesion;
infusing fluid into the blood vessel; and
aspirating fluid from the blood vessel through the evacuation sheath.

72. (new) The method of claim 71, wherein deploying the second occlusive element includes creating a seal between a guide catheter and the evacuation sheath.

73. (new) The method of claim 71, wherein deploying the first occlusive element includes creating a seal between the evacuation sheath and the blood vessel.

74. (new) The method of claim 71, wherein treating the lesion includes advancing a device across the lesion while substantially all blood flow in the vessel proximate to the lesion is stopped.

75. (new) The method of claim 71, wherein advancing the evacuation sheath into the blood vessel includes advancing the evacuation sheath through a guide catheter so that the distal portion of the evacuation sheath extends past a distal end of the guide catheter and into the blood vessel.

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76. (new) The method of claim 71, wherein infusing fluid into the blood vessel includes advancing an infusion catheter through the evacuation sheath and infusing fluid through the infusion catheter.

77. (new) The method of claim 76, wherein advancing the infusion catheter includes advancing the infusion catheter to a position such that a fluid port of the infusion catheter is distal to the lesion.

78. (new) The method of claim 71, wherein aspirating fluid from the blood vessel through the evacuation sheath includes inducing retrograde blood flow within the blood vessel to carry embolic material dislodged during treating into the evacuation sheath.

79. (new) A method of treating a lesion within a blood vessel, comprising:
advancing a guide catheter proximate to a lesion in the blood vessel to be treated;

advancing an evacuation sheath through the guide catheter so that a first portion of the evacuation sheath extends past a distal end of the guide catheter and into the blood vessel, the evacuation sheath having a sealing surface on a second portion thereof proximal to the first portion;

expanding the sealing surface to create a seal between the guide catheter and the evacuation sheath;

stopping substantially all blood flow within the vessel proximate to the lesion;

treating the lesion with a therapeutic device while substantially all blood flow within the vessel is stopped;

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infusing fluid into the blood vessel with an infusion catheter; and
aspirating fluid from the blood vessel through an evacuation lumen of the
evacuation sheath.

80. (new) The method of claim 79, further comprising advancing a guidewire
through the evacuation lumen to a position distal to the lesion to be treated.

81. (new) The method of claim 80, wherein treating the lesion includes
advancing a dilation balloon of the therapeutic device across the lesion and dilating the
lesion with the dilation balloon.

82. (new) The method of claim 80, wherein infusing fluid into the blood vessel
with an infusion catheter includes inserting the infusion catheter over the guidewire and
into the blood vessel to a position where a fluid port of the infusion catheter is distal to
the lesion.

83. (new) The method of claim 79, wherein aspirating fluid from the blood
vessel through the evacuation lumen includes inducing retrograde blood flow within the
blood vessel to carry embolic material dislodged during treating into the evacuation
lumen.

84. (new) The method of claim 79, wherein stopping substantially all blood
flow within the vessel proximate to the area to be treated includes expanding a second
sealing surface on the first portion of the evacuation sheath.

85. (new) The method of claim 84, wherein expanding the second sealing
surface includes creating a seal between the evacuation sheath and the blood vessel.

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86. (new) A method of treating a lesion within a blood vessel, comprising:
advancing a guide catheter proximate to an ostium of the blood vessel;
advancing an evacuation sheath through the guide catheter so that a first
portion of the evacuation sheath extends past a distal end of the guide catheter and into
the blood vessel;
deploying an occlusive element on a second portion of the evacuation
sheath to create a seal between the guide catheter and the evacuation sheath;
treating the lesion;
infusing fluid into the blood vessel with an infusion catheter; and
aspirating fluid from the blood vessel through an evacuation lumen of the
evacuation sheath.

87. (new) The method of claim 86, further comprising advancing a guidewire
through the evacuation lumen to a position distal to the lesion to be treated.

88. (new) The method of claim 87, wherein treating the lesion includes
advancing a dilation balloon of the therapeutic device across the lesion and dilating the
lesion with the dilation balloon.

89. (new) The method of claim 87, wherein infusing fluid into the blood vessel
with an infusion catheter includes inserting the infusion catheter over the guidewire and
into the blood vessel to a position where a fluid port of the infusion catheter is distal to
the lesion.

90. (new) The method of claim 86, wherein aspirating fluid from the blood
vessel through the evacuation lumen includes inducing retrograde blood flow within the

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blood vessel to carry embolic material dislodged during treating into the evacuation lumen.

91. (new) The method of claim 86, wherein advancing the evacuation sheath includes advancing the evacuation sheath beyond a major side branch of the blood vessel.

92. (new) The method of claim 86, further comprising deploying a second occlusive element on the first portion of the evacuation sheath to create a seal between the evacuation sheath and the blood vessel.

93. (new) The method of claim 86, further comprising stopping substantially all blood flow within the blood vessel proximate to the lesion.

94. (new) The method of claim 93, wherein treating the lesion includes advancing a device across the lesion while substantially all blood flow within the vessel proximate to the lesion is stopped.

95. (new) The method of claim 86, wherein the second portion of the evacuation sheath is proximal to the first portion of the evacuation sheath and remains within the guide catheter during the deploying step.

96. (new) A method for treating a lesion within a blood vessel, comprising:
positioning a guide catheter proximate to a lesion in the blood vessel;
positioning an evacuation sheath within the blood vessel;
prior to advancing a device across the lesion, stopping substantially all blood flow in the blood vessel proximate to the lesion;

while substantially all blood flow is stopped, advancing a guidewire through the guide catheter and the evacuation sheath and across the lesion;

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after advancing the guidewire, inducing retrograde flow of blood in the blood vessel proximate to the lesion to remove embolic debris dislodged by the guidewire;

subsequent to removing the embolic debris dislodged by the guidewire, stopping substantially all blood flow in the blood vessel proximate to the lesion;

while substantially all blood flow is stopped and after advancing the guidewire, advancing a therapeutic catheter having a dilation balloon along the guidewire to the lesion;

dilating the lesion with the dilation balloon;

removing the therapeutic catheter from the guidewire;

while substantially all blood flow is stopped and after removing the therapeutic catheter, advancing an infusion catheter having an infusion lumen and at least one fluid port over the guidewire to a position where the at least one fluid port is distal to the lesion;

infusing fluid through the infusion catheter into the blood vessel; and

aspirating fluid through an evacuation lumen of the evacuation sheath.

97. (new) An embolic protection system for treating a lesion in a blood vessel, comprising:

a guide catheter having a guidewire lumen;

an evacuation sheath configured to move within the lumen of the guide catheter and having an evacuation lumen and a sealing surface;

a guidewire configured to move within the lumen of the guide catheter and the evacuation lumen; and

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an infusion catheter having an infusion lumen, at least one infusion port, and a guidewire lumen configured to accept the guidewire, the infusion catheter being configured to move within the lumen of the guide catheter and the evacuation lumen and over the guidewire, wherein the infusion catheter guidewire lumen is shorter than the guide catheter lumen.

98. (new) The embolic protection system of claim 97, wherein the sealing surface is configured to form a seal with the guide catheter.

99. (new) The embolic protection system of claim 97, further comprising a dilation catheter having a dilation balloon at a distal end and a guidewire lumen, wherein the guidewire lumen of the dilation catheter has a first cross-sectional dimension, and the infusion catheter has a second cross-sectional dimension larger than the first dimension.

100. (new) The embolic protection system of claim 97, wherein the infusion lumen has a first length and the guidewire lumen of the infusion catheter has a second length shorter than the first length.

101. (new) The embolic protection system of claim 97, wherein the infusion catheter guidewire lumen has first and second open ends, and wherein the guidewire lumen is sized such that when a first end of the guidewire lumen is positioned distal to a distal end of the guide catheter, the second end of the guidewire lumen is positioned within the guide catheter.

102. (new) A method of treating a lesion within a blood vessel of a patient, comprising:

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inserting an evacuation sheath into the patient, the evacuation sheath having an evacuation lumen and a sealing surface on a distal portion thereof, the sealing surface configured to seal against an inner surface of a blood vessel;

positioning the sealing surface within a blood vessel proximally to a lesion to be treated;

advancing a guidewire through the evacuation lumen to position it in the blood vessel;

inserting a dilation catheter having a dilation balloon and a guidewire lumen over the guidewire and into the blood vessel to a position where the dilation balloon is proximal to the lesion;

deploying the sealing surface to occlude normal antegrade flow within the blood vessel;

subsequent to deploying the sealing surface, advancing the dilation balloon across the lesion;

dilating the lesion with the dilation catheter;

removing the dilation catheter from the guidewire;

inserting an infusion catheter having a guidewire lumen, an infusion lumen, and at least one fluid port over the guidewire and into the blood vessel to a position where the at least one fluid port is distal to the lesion;

infusing fluid through the infusion catheter; and

aspirating fluid through the evacuation sheath.

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103. (new) The method of claim 102, wherein inserting the infusion catheter includes inserting the infusion catheter subsequent to removing the dilation catheter from the guidewire.

104. (new) The method of claim 102, wherein the guidewire lumen of the dilation catheter has a first cross-sectional dimension, and the infusion catheter has a second cross-sectional dimension larger than the first cross-sectional dimension.

105. (new) The method of claim 102, wherein aspirating fluid includes inducing retrograde blood flow within the blood vessel to carry embolic material dislodged during dilating of the lesion into the evacuation lumen of the evacuation sheath.

106. (new) A method of treating a lesion within a blood vessel of a patient, comprising:

inserting an evacuation sheath into the patient, the evacuation sheath having an evacuation lumen and a sealing surface on a distal portion thereof, the sealing surface configured to seal against an inner surface of a blood vessel;

positioning the sealing surface within a blood vessel proximal to a lesion to be treated;

advancing a guidewire through the evacuation lumen to position it in the blood vessel;

advancing a dilation balloon of a dilation catheter across the lesion;

dilating the lesion with the dilation catheter;

removing the dilation catheter from the guidewire;

inserting an infusion catheter over the guidewire and into the patient to a position where at least one fluid port of the infusion catheter is distal to the lesion, the

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infusion catheter further including a guidewire lumen and an infusion lumen, wherein the guidewire lumen is configured to receive a guidewire and includes proximal and distal openings positioned such that when the infusion catheter is positioned so that the at least one fluid port is distal to the lesion, the proximal opening of the guidewire lumen is positioned within the patient; and

infusing fluid through the infusion catheter.

107. (new) An embolic protection system for treating a lesion in a blood vessel, comprising:

an evacuation sheath having an evacuation lumen and a scaling surface;

a guidewire configured to move within the evacuation lumen; and

an infusion catheter having an infusion lumen, at least one infusion port, and a guidewire lumen configured to accept the guidewire, the infusion catheter being configured to move within the evacuation lumen and over the guidewire, wherein the infusion lumen has a first length and the infusion catheter guidewire lumen has a second length substantially shorter than the first length.

108. (new) The embolic protection system of claim 107, further comprising a guide catheter having a guide lumen, wherein the infusion catheter guidewire lumen is shorter than the guide lumen.

109. (new) The embolic protection system of claim 107, further comprising a guide catheter, wherein the infusion catheter guidewire lumen has first and second open ends, and wherein the guidewire lumen is sized such that when the first end of the guidewire lumen is positioned distal to a distal end of the guide catheter, the second end of the guidewire lumen is positioned within the guide catheter.

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